SECTION E: 510(K) SUMMARY

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Physio-Control, Inc. 11811 Willow Road Northeast P.O. Box 97006 Redmond, Washington 98073-9706 Registration Number: 3015876
Contact Person	Teresa Davidson Telephone: (425) 867-4733 Fax: (425) 867-4154 email: teresa.davidson@physio-control.com
Date Summary Prepared	November 20, 2012
Device Name	TrueCPR™ COACHING DEVICE
Device Common Name	Aid, Cardiopulmonary Resuscitation
Regulation Description	External Cardiac Compressor
Device Classification	Device Class: III Product Code: LIX Classification Panel: Cardiovascular Device Regulation Number: 21 CFR 870.5200
Identification of the Legally Marketed Device (Predicate Device)	PocketCPR(K112660, K071321) and HeartStart MRx with Optional Q-CPR (K051134) Device class: III Product Code: LIX Classification Panel: Cardiovascular Device Regulation Number: 21 CFR 870.5200
Performance Standards	This 510(k) includes documentation related to the verification and validation activities supporting the safe and effective use of TrueCPR.
Description	The TrueCPR coaching device provides rescuers with real-time feedback on chest compressions during cardiopulmonary resuscitations (CPR) in accordance with current guidelines.

SECTION E: 510(K) SUMMARY (continued)

Intended Use	The TrueCPR device is intended to provide feedback to assist rescuers to perform cardiopulmonary resuscitation (CPR). Rescuers must be trained in CPR and use of the device. The TrueCPR device is intended for use on patients eight years of age and older.
Testing Types	Bench Testing (Comprehensive verification testing): • Requirements Testing • Electromagnetic Compatibility • Software Performance • Environmental • Simulated Use Testing • Biocompatibility
Technological Characteristics of subject and predicate device	Device intended use, feature and functional characteristics for predicate devices identified are substantially equivalent when compared to the proposed TrueCPR device. Importantly, no new issues of safety and effectiveness have been raised with the proposed device.
Conclusion of testing	The information in this 510(k) demonstrates that the TrueCPR COACHING DEVICE is substantially equivalent to the identified predicate devices with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Physio-Control, Inc.
c/o Teresa Davidson
11811 Willows Rd. NE
PO Box 97006
Redmond, Washington 98073-9706

Re: K123597
Trade/Device Name: TrueCPR Coaching Device
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor/CPR Aide Device
Regulatory Class: Class III (three)
Product Code: LIX
Dated: April 3, 2013
Received: April 4, 2013

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D: STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K123597

Device Name: **TrueCPR™ COACHING DEVICE**

Indications for Use:

The TrueCPR device is intended to provide feedback to assist rescuers to perform cardiopulmonary resuscitation (CPR). Rescuers must be trained in CPR and use of the device.

The TrueCPR device is intended for use on patients eight years of age and older.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

Matthew G. Hillebrenner